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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,132	02/13/2004	Saburo Kawaguchi	06082.0030	3812
22852 7590 05/15/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER EMCH, GREGORY S	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 05/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,132	Applicant(s) KAWAGUCHI ET AL.	
	Examiner Gregory S. Emch	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim 1 has been amended and claims 5-8 have been canceled as requested in the amendment filed on 20 February 2007. Following the amendment claims 1-4 are pending in the instant application.

Claims 1-4 are under examination in the instant office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,750,376 to Weiss et al. is maintained for reasons of record and as set forth below.

In the reply filed on 20 February 2007, Applicants assert that the alleged teachings in Weiss on using O-2A progenitor cells for treating demyelinated lesions do not speak to the composition of claim 1. Applicants also assert that in demyelinated

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lesions the axons themselves are left intact and that even if Weiss's preparation cured a demyelinating disease, this teaches nothing about the preparation's ability to induce regeneration of axons because the axons are intact. Weiss's apparent discussion of using neural stem progeny on animals with a transected spinal cord (col. 64) does not teach the composition of independent claim 1 either. Applicants also assert that the use of neural stem cell progeny as disclosed by Weiss et al. does not does not teach or suggest the composition of claim 1. Applicants also assert that O-2A progenitor cells and type-2 astrocyte progenitors are two different cell types and that O-2A progenitor cells are the precursors of type-2 astrocyte progenitor cells.

Applicants' arguments have been fully considered and are not found persuasive.

First, it is noted that claim 1 and dependent claims are directed to a composition in which the claimed "therapeutic agent for induction of regeneration of injured axons" descriptor is recited in the preamble and thus imparts no patentable weight on the claim (see MPEP 2111.02, section II). Therefore, whether or not the Weiss et al. reference appreciated Applicants' asserted therapeutic effect is irrelevant. Thus, for the purposes of applying prior art, the reference need only teach a composition comprising glial cells including cultured type-2 astrocyte progenitors, wherein the composition is not incompatible with a therapeutic intention. Accordingly, the composition of Weiss et al. is not incompatible with a therapeutic intention. Further, the claims recite the open language "comprising," which does not exclude additional unrecited elements (see MPEP 2111.03). Thus, the claimed composition broadly encompasses glial cells with at least type-2A astrocytes. Accordingly, given that the Weiss et al. reference teaches

mixed glial cell cultures raised *in vitro*, said cultures comprising progenitor cells that eventually give rise to type-2 astrocytes, (i.e., O-2A progenitor cells) as well as type-2 astrocytes themselves (e.g. col.20, lines 6-14), the reference anticipates the claims because the glial cells of the prior art would inherently include at least some type-2A progenitors. This is because, as evidenced by Applicants, O-2A progenitors give rise to type-2A progenitors, which give rise to type-2A astrocytes. Therefore, since the reference meets teaches all the elements of the claims (both expressly and inherently), the rejection is maintained.

The rejection of claims 1, 3 and 4 under 35 U.S.C. 102(b) as being anticipated by Groves et al. is maintained for reasons of record and as set forth below.

In the reply filed on 20 February 2007, Applicants assert that Groves appears to discuss a study in which purified O-2A progenitor cells were used to treat demyelinated lesions and that treating demyelination has nothing to do with regenerating axons. In addition, Applicants assert that as discussed above, the use of O-2A progenitor cells in Groves does not address the use of glial cells including cultured type-2 astrocyte progenitors as recited in claim 1.

Applicants' arguments have been fully considered and are not found persuasive. As stated above, claim 1 and dependent claims are directed to a composition in which the claimed "therapeutic agent for induction of regeneration of injured axons" descriptor is recited in the preamble and thus imparts no patentable weight on the claim (see MPEP 2111.02, section II). Therefore, it is irrelevant whether or not the Groves

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reference appreciated the claimed therapeutic effect. Thus, for the purposes of applying prior art, the reference need only teach a composition comprising glial cells including cultured type-2 astrocyte progenitors, wherein the composition is not incompatible with a therapeutic intention. Accordingly, given that the Groves et al. reference teaches mixed glial cell cultures raised *in vitro*, said cultures comprising progenitor cells that eventually give rise to type-2 astrocytes, (i.e., O-2A progenitor cells) as well as type-2 astrocytes themselves (p.455, ¶2), the reference anticipates the claims because the glial cells of the prior art would inherently include at least some type-2A progenitors. Furthermore, Groves et al.'s composition is not incompatible with a therapeutic intention. Therefore, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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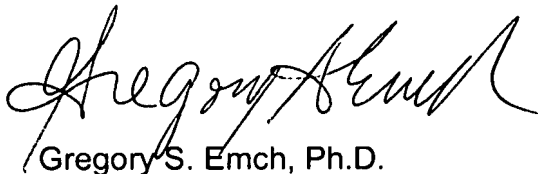
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

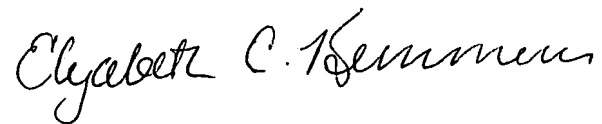
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is 571-272-8149. The examiner can normally be reached Monday through Friday from 9:00AM to 5:30PM (EST) .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
09 May 2007



ELIZABETH KEMMERER
PRIMARY EXAMINER